K062352

510(k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93) OCT 19 2006

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rebecca Lennard Regulatory Affairs Associate II Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: RLennard@dpyus.jnj.com
DATE PREPARED:	May 24, 2006
PROPRIETARY NAME:	FRS® Screw
COMMON NAME:	Bone Fixation Screw
CLASSIFICATION:	Class II device per 21 CFR 888.3040: Smooth or threaded bone fixation fastener
DEVICE PRODUCT CODE:	87 HWC
SUBSTANTIALLY EQUIVALENT DEVICES:	**DePuy SCARF THREAD-HEAD™ SCREW,** K962236, cleared on September 20, 1996 **NewDeal SA BOLD® Screw,** K011262, cleared on June 15, 2001

DEVICE DESCRIPTION:
The DePuy FRS-Screw is a cannulated thread-head screw made of a Titanium alloy and is available in lengths of 10-34mm in 2mm increments.

INTENDED USE AND INDICATIONS:

Intended Use:
The DePuy FRS-Screw is intended to be implanted for the fixation of bone fractures, fusion of a joint or bone reconstructions.

Indications for Use:
The **FRS®-Screw** is indicated for fixation of bone fractures, fusion of a joint, or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals, and carpals of the hand. Examples include:

- Hallux Valgus correction
- Akin Osteotomies

- MTP arthrodesis
- Interphalangeal arthrodesis

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy FRS®-Screw devices described in this submission are substantially equivalent to the predicate devices based on similarities in intended use, indications for use, materials and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rebecca Lennard
700 Orthopaedic Drive
Warsaw, Indiana 46582

OCT 19 2006

Re: K062352
Trade/Device Name: FRS® Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 10, 2006
Received: August 11, 2006

Dear Ms. Lennard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): _____

Device Name: ____FRS®-Screw_____

Indications for Use:

The **FRS®-Screw** is indicated for fixation of bone fractures, fusion of a joint, or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals, and carpals of the hand. Examples include:

- Hallux Valgus correction
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- MTP arthrodesis
- Interphalangeal arthrodesis

(Please do not write below this line – continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____x_____ **OR** Over-The-Counter-Use: _____

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062353